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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,853

12/14/2004

Satoshi Yonehara

10873.1578USWO

9018

52835 7590 01/05/2007

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EXAMINER

MARTIN, PAUL C

ART UNIT

PAPER NUMBER

1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,853	<b>Applicant(s)</b> YONEHARA ET AL.	
	<b>Examiner</b> Paul C. Martin	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 6-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 6-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/30/06</u>   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1, 3, and 6-21 are pending in this application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **Claim Rejections - 35 USC § 112**

The rejection of Claims 10 and 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been withdrawn due to the Applicant's amendment to the Claims filed 09/18/06.

Claims 1, 3 and 6-21 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record set forth in the Action mailed 05/18/06.

***Response to Arguments***

Applicant's arguments filed 09/18/06 have been fully considered but that are not deemed to be persuasive.

The Applicant argues that one of ordinary skill in the art would recognize the term "hemoglobin degradation product" to refer to an enzymatically digested hemoglobin (Remarks, Pg. 7, Lines 12-22).

The Applicant's argument is not found persuasive for the following reasons, how one of skill in the art would recognize an enzymatically digested hemoglobin as a "hemoglobin degradation product" as once the hemoglobin is digested or degraded it ceases to be a hemoglobin molecule and becomes a conglomeration of whatever constituent parts made up the hemoglobin. One of skill in the art would not be aware exactly which of those parts the claims of the instant application are directed, and therefore the Applicant has failed to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

***Claim Rejections - 35 USC § 102***

The rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated by Ouyang *et al.* (5,902,731), has been withdrawn due to the Applicant's amendments to the Claims filed 09/18/06.

***Claim Rejections - 35 USC § 103***

The rejection of Claims 1, 3 and 6-20 under 35 U.S.C. 103(a) as being unpatentable over Ouyang *et al.* (5,902,731) in view of Komori *et al.* (2002/0025546 A1), has been withdrawn due to the Applicant's amendments to the Claims filed 09/18/06.

Claims 1, 3 and 6-21 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Komori *et al.* (2002/0025546 A1) in view of Oshiro *et al.* (1982).

This rejection is made for reasons of record set forth in the Action mailed 12/12/05 (and extended to new claims as necessitated by the Applicant's amendment filed 09/18/06).

While neither Komori *et al.* nor Oshiro *et al.* taught the use of lithium lauryl sulfate (LLS), one of ordinary skill in the art would have recognized LLS as an obvious functional variation of the sodium lauryl sulfate used by Oshiro *et al.*, and one of ordinary skill in the art would have been motivated to make this substitution because use of alternatives and functional equivalent techniques would have been desirable to those of ordinary skill in the art based upon the economics and availability of compounds. There would have been a reasonable expectation of success in making this substitution because Oshiro *et al.* taught that the sulfonic acid compound SLS was useful in hemoglobin quantification assays, and one would expect LLS to function in an equivalent manner.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

### **Conclusion**

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

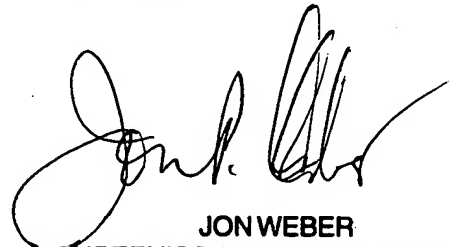
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin  
Examiner  
Art Unit 1657

12/22/06



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**